IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

MELANIE STACEL, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Case No. 08-CV-1143 Judge Joan B. Gottschall Magistrate Judge Jeffrey Cole

MEMORANDUM IN SUPPORT OF
DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S MOTION TO DISMISS

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Teva Pharmaceuticals USA, Inc. ("Teva"), through its undersigned counsel, submits this Memorandum in Support of its Motion to Dismiss Counts I through IV of Plaintiff's Second Amended Complaint.[1]

BACKGROUND

This is a products liability action for injuries allegedly suffered by Plaintiff Melanie Stacel ("Plaintiff") as a result of the use of a prescription pharmaceutical product minocycline hydrochloride ("minocycline"). Teva is a pharmaceutical company specializing in the development, production, and marketing of generic and proprietary branded pharmaceuticals. Teva is one of several companies that manufactures a generic form of minocycline, a tetracycline antibiotic commonly prescribed to treat bacterial infections, including acne and other skin infections.

It is alleged in the Second Amended Complaint and, therefore, taken as true for the purposes of this Motion only, that Plaintiff was prescribed minocycline for the treatment of acute acne, and that she began taking minocycline in July 2004. (Second Am. Compl. ¶¶ 7-8.) Plaintiff alleges further that as a result of her use of said drug, she was diagnosed with drug induced lupus in September 2005. (Second Am. Compl. ¶¶ 11-12.)

Plaintiff asserts four counts against Teva. Count I alleges a cause of action for products liability based on negligence. Count II alleges a cause of action based on common law fraud and misrepresentation. Count III alleges a cause of action based on the Illinois Consumer Fraud and

[1] On August 2, 2007, Melanie Stacel filed a Complaint against Teva, Teva Pharmaceutical Industries Ltd, and Walgreen Co. On February 28, 2008, Plaintiff filed an Amended Complaint asserting claims against only Teva. On March 28, 2008, Plaintiff filed a Second Amended Complaint asserting claims against Teva. (Teva Pharmaceutical Industries Ltd. has never been served in this action, and has not been named in the Amended Complaint or the Second Amended Complaint. Plaintiff voluntarily dismissed Walgreen Co. on February 19, 2008.)

Deceptive Business Practices Act ("Illinois Consumer Fraud Act").[2] For the reasons set forth below, all of Plaintiff's claims fail, and the Second Amended Complaint should be dismissed in its entirety.

ARGUMENT

On a motion to dismiss, the court accepts as true all well-pleaded factual allegations. If the complaint fails to state a claim upon which relief can be granted, the court should dismiss the case. *See* Fed. R. Civ. P. 12(b)(6); *R.J.R. Services, Inc. v. Aetna Casualty and Surety Co.*, 895 F.2d 279, 280-81 (7th Cir. 1989). To survive a Rule 12(b)(6) motion to dismiss, it is not enough that there might be some conceivable set of facts that entitles the plaintiff to relief. *Bell Atlantic Corp. v. Twombley*, 127 S. Ct. 1955, 1968-69 (2007). Instead, "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Id.* at 1964-65 (internal quotations omitted). Even assuming all well-pleaded facts as true (which Teva does not concede), Plaintiff's Second Amended Complaint fails to state a claim on which relief can be granted for the following reasons:

First, Counts II and III fail to properly plead the asserted causes of action based on common law fraud and the Illinois Consumer Fraud Act, respectively. Because both Counts involve allegations of fraud, they are subject to a heightened pleading standard for fraud claims imposed by Fed. R. Civ. P. 9(b), pursuant to which Plaintiff must set forth ***with particularity*** all circumstances constituting the alleged fraudulent conduct. The Second Amended Complaint does not even come close to pleading these claims with sufficient particularity. Plaintiff does not identify the content of any alleged false statements made by Teva, the time or place when such

[2] Count IV asserts a claim for punitive damages, which is contingent on the preceding three counts, and must fail if they do.

statements were allegedly made, or the method in which such statements were allegedly made. Plaintiff also fails to identify the particular federal and FDA regulations that Teva allegedly disregarded and the ways in which Teva failed to comply. Accordingly, Plaintiff's claims asserted in Counts II and III fail.

Second, Plaintiff's state law claims are preempted by the Supremacy Clause of the United States Constitution and by federal law. Federal regulations require that Teva's generic drug minocycline have the same labeling as its reference-listed drug, Minocin®, thus dictating the precise labeling that had to appear on the product that Plaintiff allegedly ingested. Federal regulations further prohibit Teva from making any changes to the labeling under threat of removal of its product from the market. As such, Teva cannot be held liable under state law for complying with mandatory federal statutory and regulatory law.

For these reasons, Plaintiff's Second Amended Complaint should be dismissed.

I. PLAINTIFF'S COMMON LAW FRAUD AND MISREPRESENTATION CLAIMS FAIL DUE TO INADEQUATE PLEADING UNDER FED. R. CIV. P. 9(b)

Count II of Plaintiff's Second Amended Complaint, which asserts common law fraud and misrepresentation claims against Teva, must be dismissed because it contains nothing more than conclusory, vague allegations supported by no specific facts or evidence. Fraud claims must meet the heightened pleading standard set forth in Fed. R. Civ. P. 9(b), which obligates Plaintiff to state ***with particularity*** the circumstances constituting fraud. This Circuit has affirmed that "[t]he liberal notice-pleading standard does not apply to claims of fraud; such claims of fraud are subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b)." *Vicom, Inc. v. Harbridge Merchant Servs.*, 20 F.3d 771, 777 (7th Cir.1994). Specifically, a pleading asserting a claim of fraud or misrepresentation must spell out (1) the identity of the person or entity that made the misrepresentation; (2) the time, place, and content of the misrepresentation;

and (3) the method by which the misrepresentation was communicated. *Id.* In the instant case, Plaintiff's claims of fraud and misrepresentation fail to meet this heightened standard.

First, Plaintiff fails to set forth with sufficient particularity the misrepresentations or false statements of material fact allegedly made by Teva. Plaintiff posits that Teva made false statements by concealing Teva's "full knowledge" of reported cases in which its minocycline drug was reported to have caused what is commonly known as lupus. (Second Am. Compl. ¶¶ 25-26.) However, Plaintiff fails to allege any specific basis for concluding that Teva had any such knowledge concerning its drug.

Second, Plaintiff fails to identify the time, place, content, or method by which Teva allegedly made such false statements to Plaintiff, Plaintiff's physicians, the public, or FDA. (Second Am. Compl. ¶¶ 26-27.)[3] Although Plaintiff claims that Teva made false statements and misrepresentations in the labeling for its minocycline product, Plaintiff fails to attach a copy to her Second Amended Complaint or to identify the purported "fraudulent" language.

Finally, while Plaintiff claims that Teva made false statements to FDA in failing to provide FDA with information concerning cases of drug induced lupus, and in failing to ask FDA to supplement the minocycline label, Plaintiff sets forth no specific facts to support her serious accusation that Teva has not complied with FDA regulations in connection with the reporting of adverse events for its minocycline drug.

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[3] Furthermore, under Illinois law, a prescription drug manufacturer, such as Teva, has no duty to provide warnings of any adverse effects associated with a drug directly to the consumer, such as Plaintiff – Teva's duty is to provide warnings to the prescribing physician only. *Kirk v. Michael Reese Hosp. & Med. Ctr.,* 513 N.E.2d 387, 393 (Ill. 1987).

In sum, Plaintiff has fallen far short of alleging with sufficient particularity the circumstances constituting the basis for her fraud and misrepresentation claims. For these reasons, Count II of the Second Amended Complaint should be dismissed.

II. PLAINTIFF'S CLAIMS UNDER THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT ALSO FAIL DUE TO INADEQUATE PLEADING UNDER FED. R. CIV. P. 9(b)

Count III of Plaintiff's Second Amended Complaint, which alleges claims under the Illinois Consumer Fraud Act, 815 ILCS 505/1, *et seq.*, must also be dismissed due to Plaintiff's failure to plead these claims with sufficient particularity. The elements for a claim under the Illinois Consumer Fraud Act include: "1) a deceptive act or practice by [the defendant], 2) [the defendant's] intent that [the plaintiff] rely on the deception, . . . 3) that the deception occurred in the course of conduct involving trade and commerce [and 4)] that the deceptive act proximately caused [the plaintiff's] injury." *Durst v. Ill. Farmers Ins. Co.*, 2006 WL 140546, at *3 (N.D. Ill. 2006). Any claim brought in federal court under the Illinois Consumer Fraud Act must be pled ***with particularity*** pursuant to Fed. R. Civ. P. 9(b). *Id.*; *see also Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 470 (7th Cir. 1999) ("Rule 9(b) requires heightened pleading of fraud claims in all civil cases brought in the federal courts, whether or not the applicable state or federal law requires a higher standard of proving fraud, which sometimes it does and sometimes it does not.") As stated *supra*, pleading with particularity means that Plaintiff must set forth the "who, what, when, and where" of the alleged fraud. *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 923 (7th Cir. 1992).

Plaintiff's allegations in Count III suffer from the same weaknesses described above with respect to Count II – Plaintiff does not provide the basis for her conclusion that Teva concealed information about its minocycline drug, and does not identify the time, place, content, or method by which Teva allegedly concealed this information. Similarly, in alleging that Teva failed to

provide adequate warnings of drug induced lupus, Plaintiff again does not specifically identify the purportedly deceptive language. Plaintiff repeats her allegations that Teva acted deceptively by failing to comply with various regulatory requirements and FDA procedures in relation to its minocycline drug. (Second Am. Compl. ¶ 34.) However, Plaintiff again fails to plead *any* specific detail constituting the purported basis of her claims that Teva did not properly report adverse events to FDA or the Adverse Event Reporting System. Nor does Plaintiff specify how Teva allegedly failed to follow FDA procedures concerning product letters of approval.

For these reasons, Count III of the Second Amended Complaint should be dismissed.

III. PLAINTIFF'S STATE LAW CLAIMS ARE PREEMPTED BY THE SUPREMACY CLAUSE OF THE CONSTITUTION AND FEDERAL LAW

Teva lawfully complied with federal law and regulations in securing the right to sell minocycline for the indications approved by FDA, with the required FDA-approved labeling. Under the doctrine of federal preemption pursuant to the Supremacy Clause of the United States Constitution and federal law, Teva cannot be held liable under state law for complying with federal statutory and regulatory law.

A. Teva Has Lawfully Complied with Federal Regulations for Generic Drug Manufacturers With Respect to Its Minocycline Product

1. FDA Strictly Regulates the Manufacture and Sale of Brand Name and Generic Prescription Drugs

The manufacture and sale of prescription drug products in the United States is a highly regulated industry, under the jurisdiction of FDA. FDA draws its statutory authority as to the approval of such manufacture and sale of drugs primarily from its enabling statute, the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., as amended by the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Amendments") (collectively, the "Food and

Drug Act" or "FDCA"), and has promulgated regulations implementing such statutes, which may be found in pertinent part at 21 C.F.R. Part 314.

Broadly speaking, under the United States' regulatory scheme, prescription drugs fall into two categories, new or branded drugs and generic drugs. A new drug is one that has not yet been established or generally recognized by persons with relevant scientific training as safe and effective for the purposes or medical indications for which its use is intended. 21 U.S.C. § 312(p). The right to manufacture and market such a drug in the United States is secured through the filing of a New Drug Application ("NDA"). In order to obtain approval of an NDA, the applicant must demonstrate the safety and efficacy of the drug for its intended indications to the satisfaction of FDA, typically through the conduct of extensive clinical trials in humans. The research and development of such drugs and the conduct of the requisite clinical trials is often a costly process, which takes years to complete. For that reason, among others, NDA drugs, which are sold under proprietary brand names, are often very expensive.

In the public policy interest of fostering competition, and promoting the availability of lower cost medical care and affordable prescription drugs, Congress and FDA enacted statutory provisions and regulations to encourage the manufacture and marketing of the other category of drugs, known as generic drugs. Specifically, the Hatch-Waxman Amendments (codified at 21 U.S.C. § 355(j), 35 U.S.C. §§ 156, 271, 281), established the current procedure for obtaining approval from FDA to market and sell a generic drug, allowing the generic maker to submit an abbreviated NDA ("ANDA"). The ANDA applicant need only demonstrate that the generic manufacturer will produce a drug product that is bioequivalent to its brand name counterpart, the so-called "reference-listed drug", and that the labeling and warnings of the generic drug are identical to that of the approved reference-listed drug. 21 U.S.C. § 355(j)(2)(A).

The requirements that a generic manufacturer must meet under the ANDA process are set forth in Section 505(j) of the Food and Drug Act, 21 U.S.C. § 355(j). Specifically, the process begins with a requirement that the information not be new or innovative, but rather wholly derivative of information already provided by the innovator manufacturer. *See* § 321(aa) (ANDA must "rel[y] on the approved application of another drug with the same active ingredient to establish safety and efficacy.") Under subsection 505(j)(2)(A), an ANDA must show:

- the conditions of use on the proposed labeling for the generic drug are the same as those approved for the listed drug [§ 505(j)(2)(A)(i)], excepting only indications covered by a patent or subject to exclusivity protection under FDCA § 505(j)(5)(D). *See* 21 C.F.R. § 314.94(a)(8)(iv); *see also* 57 Fed. Reg. at 17,961.

- the active ingredient is the same as that of the listed drug [§ 505(j)(2)(A)(ii)].

- the route of administration, dosage form, and strength are the same as those of the listed drug [§ 505(j)(2)(A)(iii)].

- the generic drug is bioequivalent to (i.e., can be expected to have the same therapeutic effect as the listed drug) [§ 505(j)(2)(A)(iv)].

H.R. Rep. No. 98-857, at 21-22.

Thus, an ANDA applicant is not required or expected to conduct clinical trials to establish the safety and efficacy of its drug. The Food and Drug Act and FDA's regulatory scheme contemplate that safety and efficacy will have been established by the pharmaceutical company who originally submitted the NDA for the reference listed drug. In contrast, the generic manufacturer is obliged only to conduct so-called "bioequivalency" studies, to establish that its dosage formulation of the generic product has the same pharmacological action in the human body as does the reference listed drug. It is this avoidance of the need for time-consuming and costly clinical trials that permits generic drugs to be brought to market quickly and at less expense.

2. Federal Regulations Require Generic Drug Manufacturers to Conform the Labeling of its Generic Drug to the Labeling of the Reference-Listed Drug

The flip side of the regulatory framework permitting an abbreviated approval process for generic drug manufacturers is that the labeling, *i.e.* the prescribing information or package insert of the generic drug, may not deviate in any material respect from that of its reference-listed drug. Federal law requires that, but for differences relating to the fact of the product being manufactured by a different company, chiefly physical description, inactive ingredients, and omitted indications, the generic manufacturer's labeling, including all statements as to warnings, precautions, contraindications, and adverse reactions, must adhere letter for letter to the language in the corresponding provisions of the labeling of the reference-listed drug. *See* Section 505(j) of the Food and Drug Act, 21 U.S.C. § 355(j)(2)(A)(v), which requires an ANDA applicant to submit to FDA,

> information to show that *the labeling proposed for the new drug is the same as the labeling approved for the listed drug* referred to in clause (i) except for changes required because . . . the new drug and the listed drug are produced or distributed by different manufacturers.

(emphasis added.)[4] Accordingly, for generic drug manufacturers, such as Teva, the use of label language as to warnings, precautions, contraindications, and adverse reactions prescribed by FDA in its regulatory capacity is *mandatory*, *i.e.* language from which the manufacturer *may not deviate*.

[4] *See also* 21 C.F.R. § 314.94(a)(8)(i) (generic drug manufacturer must provide a copy of the currently approved labeling for the reference-listed drug); 21 C.F.R. § 314.94(a)(8)(iv) (generic manufacturer must submit side-by-side comparison of its proposed labeling with the approved labeling for the reference-listed drug, with all differences annotated and explained; no differences permitted, except as enumerated therein); 21 C.F.R. § 314.127(a)(7) (FDA will refuse to approve an ANDA if information submitted is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug").

(a) The "Changes Being Effected" regulation does not provide an exception to the rule mandating conformation of generic drug labeling to that of the reference-listed drug

At all times throughout the life of the product, the generic label must be maintained in conformity with that of the reference-listed drug, on pain of withdrawal of approval of the ANDA.[5] While it has sometimes been argued that an ANDA holder has a right to enhance warnings through the mechanism of 21 C.F.R. § 314.70(c)(6)(iii)(A), the so-called "Changes Being Effected" ("CBE") provision, FDA recently reaffirmed that this is an improper interpretation of its regulations. In the January 16, 2008 Federal Register, FDA published proposed amendments to its rules governing changes to approved labeling, wherein FDA unambiguously stated:

> CBE changes are not available for generic drugs approved under an abbreviated new drug application under 21 U.S.C. 355(i). To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug. *See* 21 CFR 314.150(b)(10); *see also* 57 FR 17950, 17953, and 17961.

73 Fed. Reg. at 2849 n.1 (Jan. 16, 2008).[6]

This is not a new interpretation of FDA regulations. Rather, this proposed rulemaking expressly is meant to codify FDA's long-standing position that under 21 C.F.R. § 314.70(c), *no labeling changes can be made unilaterally by a generic manufacturer. Id.* at 2852. On the occasion of the publication of the Final Rulemaking on ANDA Regulations in 1992, FDA clearly rejected any notion that the CBE regulation applies to generic drug manufacturers: "[a]fter approval of an

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[5] *See, e. g.*, 21 C.F.R. § 314.150(b)(10): "FDA may notify the applicant . . . [that it will] . . . withdraw approval of the application or abbreviated new drug application . . . if the agency finds . . . [t]hat the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the listed drug."

[6] Attached hereto as Exhibit A.

ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." *Abbreviated New Drug Application Regulations, Final Rule,* 57 Fed. Reg. 17950, 17961 comm. 40 (April 28, 1992).[7] FDA also expressly rejected public requests that ANDA applicants be allowed unilaterally to change or deviate from the labeling of the innovator drug to add contraindications, warnings, precautions, adverse reactions, and other safety related information:

> Two comments said the labeling provisions should be revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information.
> * * *
> *FDA disagrees with the comments. Except for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the [Food and Drug Act], the ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval.*

Id. (emphasis added).

This long-held position is made even more abundantly clear by the admonishment in the November 1999 FDA Guidance[8] and the April 2004 Revision I to that Guidance that "[a]ll labeling changes for ANDA products must be consistent with § 505(j) of the Act," (FDA Guidances at 24), *i.e.*, must conform exactly to the labeling of the reference-listed drug. Further, FDA in a December 24, 1996 letter cautioned ANDA holders that they cannot adopt innovator labeling that has been unilaterally revised by the innovator through the mechanism of 21 C.F.R. § 314.70(c), unless and until such revised innovator drug labeling has been affirmatively approved by the agency. The letter stated that "[t]he FDA must still review, possibly recommend changes and approve the [revised innovator

[7] Attached hereto as Exhibit B.
[8] Attached hereto as Exhibit C.

drug] labeling before it is acceptable for use as model labeling for an [ANDA] product." Letter from Douglas L. Sporn, Director, Office of Generic Drugs, Center for Drug Evaluation and Review at 8.[9] *See also* 57 Fed. Reg. at 17957, 17961; FDA Guidance at 24.

In addition to rulemakings and guidances, FDA has taken the same position in various *amicus curiae* briefs. As recently as December 21, 2007, FDA submitted an *amicus curiae* brief at the invitation of the United States Supreme Court, in which the agency explained that "[u]nder a correct reading of Section 314.70, [the generic drug manufacturer] could not have changed the labeling without prior FDA approval." Brief for United States as *Amicus Curiae* on Petition for a Writ of Certiorari, *Wyeth v. Levine*, No. 06-1249 (U.S. Dec. 21, 2007).[10]

3. Teva Has Complied With FDA's Requirements With Respect to the Labeling of Teva's Minocycline Product

In or about 1992, Teva first received approval of an ANDA for minocycline, a generic version of the reference-listed drug Minocin®. In compliance with federal regulations discussed *supra*, Teva conducted tests demonstrating to FDA that its minocycline product was bioequivalent to Minocin®. Teva conformed its minocycline labeling in all material respects,

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[9] Attached hereto as Exhibit D.

[10] Attached hereto as Exhibit E. FDA has asserted the same position in other recent *amicus* briefs to the Supreme Court. *See* Brief for United States as *Amicus Curiae* Supporting Respondent, *Riegel v. Medtronic, Inc.*, No. 06-179 (U.S. Oct. 19, 2007) (attached hereto as Ex. F); Brief for United States as *Amicus Curiae* Supporting Petitioners, *Warner-Lambert Co., LLC v. Kent*, No. 06-1498 (U.S. Nov. 28, 2007) (attached hereto as Ex. G). Similarly, in December 2006, FDA filed an *amicus* brief to the Third Circuit, in which it again squarely addressed this issue:

> For a generic drug manufacturer, there is no statutory or regulatory provision permitting a labeling change to be made without prior FDA approval. To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug. *See* 21 C.F.R. § 314.150(b)(10); *see also* 57 Fed. Reg. 17,950, 17953, 17,961 (1992). If a generic drug manufacturer believes that new safety information should be added to the label for its drug, it is directed to contact FDA with "adequate supporting information."

Brief for United States as *Amicus Curiae, Colacicco v. Apotex, Inc.*, No. 06-3107, at 7-8 (3rd Cir. Dec. 4, 2006) (attached hereto as Ex. H). *See also* Brief for United States as *Amicus Curiae*, *Colacicco v. Apotex, Inc.* (E.D. Pa. 2006) 432 F.Supp.2d 514 (Civ. No. 05-CV-05500) (attached hereto as Ex. I).

including Warnings and listed Adverse Reactions, to FDA-approved label for Minocin®. Any deviation from Minocin's® FDA-approved label would have rendered Teva's product misbranded, unapprovable, and unsaleable in the United States.

B. Plaintiff's State Law Claims Create an Impermissible Conflict With Federal Law

Plaintiff's state law claims alleging that Teva failed to provide adequate warnings and instructions in the marketing of its minocycline product create an impermissible conflict because they seek to hold Teva liable for complying with federal law. Accordingly, Plaintiff's state law claims are preempted and should be dismissed.

The Supremacy Clause of the United States Constitution, article VI, clause 2, preempts any state law that conflicts with the exercise of federal power. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 102 S. Ct. 3014 (1982). "Pre-emption may be either express or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Matter of Cajun Elec. Power Co-op., Inc.*, 109 F.3d 248, 253-54 (5th Cir. 1997) (*citing Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). This so-called conflict-preemption occurs where "[a] state common-law claim directly conflict[s] with a federal regulation . . . or if it [is] impossible to comply with any such regulation without incurring liability under state common law." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002). Where FDA has specifically stated that a generic drug manufacturer may not vary its drug label from that of the reference-listed drug, and that such a variation justifies withdrawal of ANDA approval, Plaintiff's state law claims requiring Teva to do just that make it impossible for Teva to comply with both federal and state law. As such, Plaintiff's claims are preempted.

C. Plaintiff's State Law Claims Impermissibly Pose an Obstacle to Congressional Objectives in Enacting the Hatch-Waxman Amendments

In addition to the actual conflict between Plaintiff's state law claims and federal law, Plaintiff's claims also impermissibly "stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). "A state law claim . . . is preempted if it interferes with the methods by which the federal statute was designed to reach [its] goals." *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987).

Plaintiff's state law claims stand as an "obstacle" to the purposes and objectives of Congress in that these claims seek to impose a duty on generic drug manufacturers, such as Teva, to continually develop and strengthen warning labels, undermining a key purpose of the Hatch-Waxman Amendments – to promote competition from generic drugs by *relaxing* the generic drug approval and labeling process. Under the Hatch-Waxman Amendments, Teva is required to maintain the language of its minocycline labeling identical to the reference-listed Minocin® drug. Thus, any attempt to impose a duty on Teva to include a different warning on its minocycline labeling from the labeling of Minocin® stands as an obstacle to Congress' objectives in enacting the Hatch-Waxman Amendments and the FDCA's implementing regulations. Accordingly, Plaintiff's state law claims are preempted and should be dismissed.

D. FDA Regulations Have Broad Preemptive Effect and Mandate Dismissal of Plaintiff's State Law Claims

Both FDA's own interpretation of its regulations and interpretive case law instruct that FDA regulations have broad preemptive effect. The Supreme Court has repeatedly recognized that in the absence of clearly expressed Congressional intent (which is absent here), FDA's position on the preemptive scope of its regulatory authority is *dispositive* so long as it is based on a permissible construction of the statute. *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Medtronic, Inc v. Lohr.*, 518 U.S. 470, 496 (1996) ("[t]he

agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and, therefore, whether it should be preempted'") (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). The same deference applies to "an agency's [reasonable] construction of its own regulations." *Martin v. Occupational Safety and Health Review Commission*, 499 U.S. 144, 150 (1991). "Congress has delegated the responsibility for administering the FDCA to FDA; such responsibility implies the authority and expertise to determine which state laws conflict with its regulations." *In re Bextra and Celebrex Marketing Sales Practices and Products Liab. Litig*, 2006 WL 2374742, at *7 (N.D. Cal. Aug. 16, 2006).

FDA has directly addressed preemption in products liability cases, and has decisively confirmed that its regulations have broad preemptive effect. In January 2006, the agency issued a new Final Rule On Requirements On the Content and Format of Labeling for Human Prescription Drug and Biological Products ("Final Rule on Labeling")[11], wherein it argues that it interprets the Food and Drug Act and its own regulatory scheme thereunder to establish both a floor and a ceiling for the disclosure of risk information. FDA states that it carefully controls the content of drug labeling as its principal tool for educating health care professionals about the risks and benefits of approved products, and notes that requirements of additional disclosures are not necessarily protective of patients, but may erode and disrupt the careful representations of those risks and benefits. The agency concludes that state law conflicts with and stands as an obstacle to the achievement of the full objectives and purposes of federal law if it purports either to compel

[11] Comment 13, the relevant portion of this extensive document, is attached hereto as Exhibit J.

the inclusion of warning language the agency has considered and found scientifically unsubstantiated or to preclude the inclusion of language the agency has deemed appropriate.

FDA reaffirmed this position in its January 16, 2008 proposed amendments to its rules, stating unequivocally:

> Federal Law governs not only what information must appear in labeling, but also what information may not appear.
>
> * * *
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> To the extent that state law would require a sponsor to add information to the labeling for an approved drug . . . without advance FDA approval based on information or data as to risks that are similar in type or severity to those previously submitted to FDA, or based on information or data that does not provide sufficient evidence of a causal association with the product, such a state requirement would conflict with federal law.

73 Fed. Reg. at 2850 n.3, 2853 (Jan. 16, 2008).[12]

FDA's expansive view of its preemptive authority is entitled to deference. However, one need not go nearly as far as does the agency to conclude that preemption is appropriate as to *generic* labeling, where the ANDA holder literally has no freedom of action with respect to label content. In fact, on May 25, 2006, the *Colacicco* district court accepted the arguments urged by

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[12] In addition to the recent rulemaking, FDA has taken the same position in recent *amicus curiae* briefs, stating unequivocally: "FDA's approval of a drug, including its labeling, generally preempts state law claims challenging the drug's safety, efficacy, or labeling." Brief for United States as *Amicus Curiae* on Petition for a Writ of Certiorari, *Wyeth v. Levine*, No. 06-1249 (U.S. Dec. 21, 2007). The Solicitor General explained:

> FDA interprets the FDCA to establish both a 'floor' and a 'ceiling' with respect to drug labeling. FDA's approval of labeling for a new drug reflects FDA's expert judgment that the labeling strikes the appropriate balance. Where . . . FDA was presented with information concerning the relevant risk, a jury's imposition of liability based on a drug's FDA-approved labeling would interfere with FDA's expert judgment.

Id. (citation omitted). *See also* Brief for United States as *Amicus Curiae* Supporting Respondent, *Riegel v. Medtronic, Inc.*, No. 06-179 (U.S. Oct. 19, 2007); Brief for United States as *Amicus Curiae* Supporting Petitioners, *Warner-Lambert Co., LLC v. Kent*, No. 06-1498 (U.S. Nov. 28, 2007); Brief for United States as *Amicus Curiae*, *Colacicco v. Apotex, Inc.* (E.D. Pa. 2006) 432 F. Supp. 2d 514 (Civ. No. 05-CV-05500).

FDA and granted summary judgment to defendant, generic drug manufacturer Apotex:

> Accordingly, we find that state tort law which would hold a generic drug manufacturer liable for failing to modify a label when, pursuant to the Hatch-Waxman Amendments to the FDCA, the ANDA approval process required that the labeling be the same as that approved for the innovator drug, and when the FDA would have deemed any post-approval enhancements "false or misleading," would actually conflict with the FDCA. For these reasons, as well as our conclusion that we must afford deference to the FDA's position that the claims are preempted, we find that Plaintiff's failure-to-warn claims are impliedly preempted.

432 F. Supp. 2d at 537-38.[13]

Inescapably, Teva was disabled by federal law and regulations from varying the mandated label language of its minocycline product, and cannot be held liable under state law for not doing so. Insofar as Teva's alleged liability under any asserted claim for relief is premised, wholly or in part, on its compliance with the Food and Drug Act or any FDA regulations promulgated thereunder, with respect to the content of the labeling of Teva's minocycline product, such claims are preempted and should be dismissed. This is true whether such claims are clothed in the guise of negligence, fraud, or misrepresentation.

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[13] On April 8, 2008, the Third Circuit rendered its decision, upholding the *Colacicco* district court's ruling that the appellant's state law claims are preempted by federal law. *Colacicco v. Apotex, Inc.*, No. 06-3107, 2008 WL 927848 (3rd Cir. Apr. 8, 2006) (attached hereto as Ex. K). Because the Third Circuit's holding rested on FDA's direct rejection of the warning proffered by the appellant, the court did not reach the broader issue of "generic" preemption addressed by the lower court. *See also In re Bextra*, *supra*, at *7, in which the court held that FDA's claims of preemption in the January 2006 Final Rule on Labeling are entitled to deference:

> [T]he FDA is the agency charged with administering the FDCA and striking a "somewhat delicate balance" among its statutory objectives. . . . The FDA is in a better position than the Court to determine whether state laws that encourage manufacturers to propose defensive labels upset the FDA's careful balance of statutory objectives.

(citation omitted). This Court need not go as far as the expansive *In re Bextra* view of preemption to conclude in this case, as did the *Colacicco* district court, that the claims against Teva ineluctably conflict with FDA authority and regulation.

CONCLUSION

For the foregoing reasons, Plaintiff's Second Amended Complaint should be dismissed.

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